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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,897	11/28/2000	Gustave Bergnes	CYTOP009C5	1088

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,897

Applicant(s)

BERGNES ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,50,51 and 60-67 is/are pending in the application.
- 4a) Of the above claim(s) 60-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31 and 50 is/are rejected.
- 7) ☒ Claim(s) 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of 9-30-02 has been fully considered. While the amended claim 31 has overcome the 112/1st and 2nd paragraphs as well as the 102 rejection based on **Kazhevnikov et. al.** and **Debnath et. al.**, it has not overcome the 102 and 103 rejections based on **Chenard et. al.** Also, the declaration of Dr. Bergnes has overcome the enablement rejection. The double patenting rejection has also rendered moot since the quinazolinone compounds with -NH(R₄) has been deleted from application 09/ 699,047. Thus, the previous rejections of 112/1st and 2nd paragraphs and double patenting are withdrawn herein. However, the 102 and 103 rejections based on **Chenard et. al.** are maintained along with a new ground of rejection.

New claims 60-67 are herein withdrawn from consideration since the composition ~~and~~ ~~method~~ claims were never presented originally.

Claims 31, 50, 51 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **New Matter:** Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. There is no support for a quinazolinone compound with R₄ as "heterocyclyl".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 31, and 50 are rejected under 35 U.S.C. 102(b)/(e) as being anticipated by **Chenard et. al.** (EP'310, EP'568, and US'812). The rejection is maintained for reasons stated in the previous action. That is, the claimed formula embraces compound in Example 10 of

EP'310; the compound on line 13 (page 7) of EP'568, and compound on line 50 (column 28) of US'812.

Applicant argue that because the claimed compound has the R-configuration, the instant variables R_2 and R_2' cannot be the same. However, in chemistry, the R- or S-configurations are simply spatial orientation of substituents on a chiral carbon. Thus, it does not matter whether substituents are the same or not. Unless expressly stated, the claims as written do not dictate R_2 and R_2' to be different by merely reciting a R-configuration.

Although Chenard et. al. do not list their compound as S- or R-configuration, such a configuration can be recognized by one skilled in the art when looking at a chiral center. Thus, the racemate disclosed by Chenard et. al. embraces the R-configuration of a quinazolinone compound claimed herein.

Claim 50 is anticipated now because it recites R_4 as benzyl without an indication of being unsubstituted. Thus, it must be taken broadly to include substituted benzyl as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 31 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Chenard et. al.** The rejection is maintained or reasons stated previously, and the one stated in the above 102 rejection regarding the R-configuration.

Claim Objections

4. Claim 51 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Chenard et. al. do not teach a species as recited in claim 51, nor do they disclosed a pharmaceutical composition comprising a vinca alkaloid or topoisomerase I inhibitor in combination with a quinazolinone compound as claimed herein.

Information Disclosure Statement

5. The information disclosure statement filed 9-30-02 and 9-10-02 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

a. The IDS of 9-10-02 is missing a page as there is no page "2 of 2" following page "1 of 2". Furthermore, no copy of references is provided.

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- b. The IDS of 9-30-02 lists references that appear to be either a database or catalog. It is uncertain which section of said database or catalog applicant wishes to have considered. Applicant is suggested to provide the relevant section(s) for consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

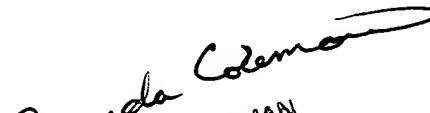
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

December 13, 2002


BRENDA COLEMAN
PRIMARY EXAMINER